IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	CIV. NO. 20-1320

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

In the face of the COVID-19 pandemic, there has been a massive, nationwide effort to meet patients' medical needs without unnecessary travel and in-person interactions that facilitate viral spread. To meet these dual goals, clinicians in virtually every area of health care are relying on telemedicine: the use of technology to connect patients with health care professionals who are not in the same physical location. Indeed, the Centers for Disease Control and Prevention ("CDC") within Defendant U.S. Department of Health and Human Services ("HHS") have issued guidance that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19." Accordingly, Defendants HHS and U.S. Food and Drug Administration ("FDA") have taken substantial action both to encourage telemedicine use and to give clinicians the flexibility—even for highly regulated drugs—to allow their patients to forgo unnecessary in-person visits where appropriate in the clinician's medical judgment.

But there is a striking exception. During the pandemic, Defendants continue to subject mifepristone, one of two FDA-approved prescription drugs used in combination to end an early pregnancy or to manage a miscarriage, to a Risk Evaluation and Mitigation Strategy ("REMS") that jeopardizes the health and safety of patients and clinicians by mandating unnecessary travel and personal interactions. Specifically, Defendants require that the mifepristone pill be dispensed only in the prescriber's hospital, clinic, or medical office ("the Mifepristone In-Person Dispensing Requirement" or "the Requirement"). Patients who have already been evaluated by a clinician through telemedicine or at a prior in-person visit are not allowed to fill their mifepristone prescription by mail. Instead, they must travel to one of these clinical settings to pick up the pill—even if they are receiving no in-person medical services at that time, and even if they will swallow the medication later at home (as the FDA permits). Of the more than 20,000 drugs regulated by

the FDA, mifepristone is the *only* one patients must obtain at a hospital, clinic, or medical office, yet may self-administer unsupervised at home.

At the best of times, the Mifepristone In-Person Dispensing Requirement lacks any medical benefit, needlessly burdens patients, and is opposed by medical experts for both reasons. During a pandemic, when unnecessary travel and personal interactions threaten patients' lives, it is profoundly counterproductive. Indeed, the CDC's COVID-19 guidance specifically advises patients to obtain medications via mail-order delivery wherever possible to mitigate risk. If not for the Requirement, patients who have obtained a prescription for mifepristone via telemedicine could do just that: obtain this safe and effective medication, which has been FDA-approved for 20 years, at home by mail without facing needless SARS-CoV-2 exposure. Instead, Defendants are forcing patients to put themselves at increased risk of COVID-19 as a condition of obtaining abortion or miscarriage care, while also needlessly raising exposure risks for clinicians.

Defendants' treatment of mifepristone is unique. In response to the public health emergency, Defendants have waived enforcement of other REMS requirements necessitating in-person visits, such as those requiring laboratory testing or magnetic resonance imaging ("MRIs") before certain drugs may be prescribed, and worked together with other federal agencies to suspend required in-person medical evaluations before many controlled substances, including opioids, may be prescribed. For the past two months, leading medical and public health experts, including Plaintiffs the American College of Obstetricians and Gynecologists ("ACOG") and the New York State Academy of Family Physicians ("NYSAFP"), as well as hundreds of other medical associations, leading health care institutions, and individual clinicians and researchers, have petitioned the FDA to likewise afford mifepristone prescribers the discretion to eliminate unnecessary in-person visits, consistent with their best clinical judgment, during this crisis.

Despite this national medical consensus, Defendants have chosen to maintain the Mifepristone In-Person Dispensing Requirement—all while continuing to stress the life-saving importance of telemedicine and mail-order prescriptions, and even as the United States continues to see tens of thousands of new confirmed SARS-CoV-2 cases, and more than a thousand new COVID-19 deaths, every day. Defendants' refusal to lift this wholly unnecessary restriction during the pandemic imposes particularly severe risks for people with lower incomes and people of color, who comprise the majority of impacted patients, and who are suffering severe illness and dying from COVID-19 at vastly higher rates than others.

Plaintiffs are likely to prevail in proving that the Requirement, which mandates life-threatening viral exposure risks as a condition of obtaining abortion or miscarriage care with no countervailing medical benefit, violates the U.S. Constitution. It unduly burdens the right to abortion, and irrationally discriminates against mifepristone patients and prescribers, subjecting them to a unique, dangerous restriction in violation of equal protection.

Plaintiffs represent tens of thousands of clinicians providing abortion and miscarriage care to patients across the nation, as well as the department chairs of obstetrics and gynecology at nearly 150 universities throughout the country. Enjoining enforcement of the Requirement will cause Defendants no harm while significantly mitigating COVID-19 risks for patients who will need mifepristone throughout 2020 and into at least 2021—until there is widespread public access to a vaccine—as well as their families, their clinicians, and the public at large.

II. FACTS

A. Mifepristone Regimen and Safety

1. Medication Abortion Regimen

The FDA approved mifepristone two decades ago as part of a regimen to end an early pregnancy. Compl. Ex. 1 (mifepristone labeling). The regimen involves two medications:

mifepristone (marketed under the brand name Mifeprex® and as a generic),[1] and misoprostol. Decl. of Allison Bryant Mantha, M.D., M.P.H., FACOG, attached hereto as Exhibit 1 ("Bryant Decl.") ¶ 27. Together, they cause the patient to undergo a pregnancy termination within a predictable time period in a manner that is clinically very similar to an early miscarriage. *Id.* To date, more than four million people in the United States have used the mifepristone-misoprostol regimen, with medication abortion comprising 39% of all U.S. abortions in 2017 (the latest available data). *Id.* ¶ 37. Medication abortion is typically prescribed up to 10 or 11 weeks of pregnancy, as dated from the patient's last menstrual period ("LMP"). *Id.* ¶¶ 28-29.

The mifepristone-misoprostol regimen is as follows: *First*, the prescribing clinician assesses the patient's eligibility. Sometimes this will occur through an in-person assessment, such as an ultrasound and/or blood work, and sometimes entirely through telehealth (for patients with regular periods and no risk factors) based on the patient's reported results of over-the-counter urine pregnancy test(s), LMP, medical history, and any symptoms. *Id.* ¶ 30. The FDA does not dictate where or how this eligibility assessment is conducted; it is left to the clinician's medical judgment and may occur entirely through telehealth technologies. Indeed, during the pandemic, Plaintiff ACOG has issued guidance specifically recommending that clinicians consider performing these assessments remotely to mitigate COVID-19 spread. *Id.*

If, based on a remote evaluation, the patient is eligible for a medication abortion without an in-person assessment, the clinician will comprehensively counsel the patient about the risks of, and alternatives to, the medication abortion regimen, including reviewing certain information

[1] Except where otherwise noted, *see infra* pages 18-19, 31, Plaintiffs use the terms "mifepristone" and "Mifeprex" interchangeably: Mifeprex® and its generic, mifepristone, are subject to a shared REMS program. *Approved Risk Evaluation and Mitigation Strategies (REMS): Mifepristone, Shared System REMS*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last visited May 25, 2020).

required by the mifepristone REMS. *Id.* ¶ 31. If the patient is eligible for and has consented to a medication abortion, the prescriber issues a prescription for mifepristone and misoprostol, and gives the patient specific instructions for use and follow-up care. *Id.*

Second, the patient picks up their prescription for mifepristone—a single 200 mg tablet—at the prescriber's hospital, clinic, or medical office. *Id.* ¶ 32. Because of the Mifepristone In-Person Dispensing Requirement, discussed *infra*, the patient must travel in person to the health care facility to obtain this pill, even if the eligibility assessment was done through telehealth and they are obtaining no in-person services. *Id.* At that time, the patient will also sign a form required by the mifepristone REMS containing the same information the prescriber and patient have previously reviewed, which, incidental to the Requirement, must be signed onsite. *Id.*

Third, the patient takes the mifepristone orally. The FDA allows patients to swallow the mifepristone wherever they feel most comfortable, including at home. *Id.* ¶ 33.

Fourth, 24 to 48 hours later and also at a location of their choosing, the patient takes the misoprostol—which is not subject to a REMS and may be obtained at the same time as the mifepristone, or from a pharmacy. *Id.* ¶ 34. Approximately 2 to 24 hours after taking that second medication, the patient experiences bleeding and cramping that expels the pregnancy. *Id.* ¶ 35.

Finally, patients follow up with their prescriber 7 to 14 days after completing the medication abortion regimen, often by telephone, to ensure the abortion was successful. *Id.* ¶ 36.

2. Early Pregnancy Loss (Miscarriage) Regimen

While misoprostol alone has long been used to medically manage early pregnancy loss, it is now widely recognized that the superior miscarriage treatment regimen includes mifepristone. *Id.* ¶ 38. Mifepristone enhances the efficacy of the misoprostol, making it more likely that the patient will completely expel the pregnancy with medications alone rather than requiring a follow-up procedure to evacuate the uterus. *Id.* ¶ 39.

Patients experiencing early pregnancy loss do not always obtain treatment when and where they first receive the miscarriage diagnosis. *Id.* ¶ 88. Patients may need additional time to process the diagnosis, or prefer to wait and see if the miscarriage resolves on its own, before deciding to undergo medical treatment. *Id.* In addition, pregnant patients who present to an emergency department with bleeding or pain and receive a miscarriage diagnosis are particularly likely to be referred elsewhere for treatment during the pandemic, when hospital resources are stretched thin and exposure risks increase the longer a patient spends in the hospital. *Id.*

3. Mifepristone Safety

According to the FDA, "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare." *Id.* ¶ 41. The FDA has observed that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, generally far below 0.1% for any individual adverse event." *Id.* ¶ 42.

The specific serious complications identified in the FDA-approved labeling for Mifeprex are "Serious and Sometimes Fatal Infections or Bleeding." Compl. Ex. 1, at 1-2. The labeling specifies that such "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth"—i.e., any time the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established." *Id.* at 2, 16.

Carrying a pregnancy to term poses much higher risks of both morbidity and mortality than medication abortion. Bryant Decl. ¶ 47. In the United States, a person is approximately 14 times more likely to die if they continue a pregnancy to term rather than have an abortion. *Id.*

B. FDA Regulation of Mifepristone

The FDA imposed the Mifepristone In-Person Dispensing Requirement in 2000, when it originally approved mifepristone.[2] Since 2011, the FDA has imposed this and other restrictions on mifepristone under its "REMS" authority.[3] Leading medical authorities, including Plaintiff ACOG, have long opposed these requirements as medically unnecessary and burdensome.[4]

A REMS is a set of restrictions beyond a drug's labeling that the FDA may properly impose only when necessary to ensure that a drug's benefits outweigh its risks. 21 U.S.C. § 355-1(a)(1). The most burdensome category are "Elements to Assure Safe Use" ("ETASU"), which the FDA is authorized to impose on a drug only if it is "associated with a serious adverse drug experience" such that it "can be approved only if, or [approval] would be withdrawn unless, such elements are required." *Id.* § 355-1(f)(1)(A). The mifepristone REMS contains three ETASU:[5]

- *First*, the **In-Person Dispensing ETASU** ("ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) provides that mifepristone may be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a "certified prescriber" (defined *infra*).

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[2] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., *Risk Assessment and Risk Mitigation Review(s)* 7 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf [hereinafter "FDA 2016 REMS Review"]. Because this document is a package of memoranda and letters, Plaintiffs' pin-cites refer to the page number within the 37-page PDF.

[3] *Id.* at 7.

[4] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., *Cross-Discipline Team Leader Review* 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf (discussing letters submitted by ACOG, the American Public Health Association, and other authorities asking FDA to eliminate the REMS, including the in-person dispensing requirement); *see also, e.g.*, Letter from Michael Munger, M.D. FAAFP, Am. Academy of Family Physicians, to Norman Sharpless, M.D., U.S. Food & Drug Admin. (June 20, 2019), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf.

[5] *See generally* Compl. Ex. 2 (Mifepristone REMS).

Patients may not obtain mifepristone by prescription from a mail-order or retail pharmacy as they would for virtually any other drug, nor even receive the medication directly by mail from their prescriber where state law allows. Instead, patients must be handed their prescription only at a hospital, clinic, or medical office, even when—as the REMS permits—they will be receiving no in-person services and will swallow the pill at home. Of the 16 drugs subject to ETASU C, mifepristone is the only one for which patients may self-administer the medication without clinical supervision. Bryant Decl. ¶ 58.

- *Second*, the **Prescriber Certification ETASU** ("ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)) requires that clinicians who seek to prescribe mifepristone fax to the drug distributor a form attesting to their clinical abilities; agreeing to comply with certain reporting requirements; and agreeing to comply with the other REMS elements.
- *Third*, the **Patient Form ETASU** ("ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)) provides that the prescriber and patient review and sign a special form with information about the mifepristone regimen and risks, and that the prescriber provide the patient with a copy and place a copy in the patient's chart. This counseling need not happen immediately before the patient signs: prescribers may conduct such counseling via telemedicine and then obtain a signature when the patient presents at the hospital, clinic, or medical office to be handed the prescription. All of the information in the Patient Form is also included in the Medication Guide that is part of the mifepristone labeling and comes with the prescription. In 2016, the FDA's expert review team and Director of the FDA's Center for Drug Evaluation and Research recommended eliminating this ETASU because it is "duplicative of information in the Medication Guide," "does not add to safe use

conditions," and "is a burden for patients," but were overruled by the Commissioner.[6]

Both the Prescriber Certification and the Patient Form ETASUs contain language assuming that the prescriber and patient are in the same physical location. The Patient Form states that the patient signed it "in my [the prescriber's] presence after I counseled her and answered all her questions," and that the prescriber "give[s] 1 copy [of the form] to the patient before she leaves the office and put[s] 1 copy in her medical record."[7] The Prescriber Certification echoes this language and also requires that the prescriber—who, because of the extremely unusual onsite dispensing requirement, must effectively also act as the pharmacist—"[r]ecord the serial number from each package of mifepristone in each patient's record."[8] *See* Bryant Decl. ¶ 70 n.24. These requirements are incidental to the Mifepristone In-Person Dispensing Requirement and encompassed by Plaintiffs' use of the term herein.

C. COVID-19 in the United States

1. Current Impact of the Pandemic

COVID-19 is the disease caused by a novel coronavirus, SARS-CoV-2, that has swept the globe. The United States is now the epicenter of the COVID-19 pandemic. Only four months since the first confirmed case of SARS-CoV-2 on U.S. soil,[9] the CDC reports more than 1.5 million cases and nearly 100,000 deaths in the United States—the highest number of COVID-19 cases and related deaths in any country in the world. Declaration of Arthur Reingold, M.D., attached hereto

[6] FDA 2016 REMS Review, *supra* note 2, at 2; U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., *Summary Review* 25 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf.
[7] Compl. Ex. 2, at 8.
[8] *Id.* at 6.
[9] The first confirmed U.S. COVID-19 occurred on January 22, 2020. *See Cases in the U.S.*, U.S. Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last visited May 25, 2020).

as Exhibit 2 ("Reingold Decl.") ¶ 27.[10] Indeed, the case and death tally in certain U.S. *states* exceeds that of most countries in the world. *Id.* As of May 20, in a single day, more than 23,000 new cases and 1,300 new deaths were being reported in the United States. *Id.*

Significantly, COVID-19's harms have not been borne equally. The available data show a particularly high prevalence of infection in areas with lower average incomes. *Id.* ¶ 51. This higher prevalence is likely due to the fact that many people with lower-paying employment have neither the flexibility to work from home nor the financial cushion to forgo working, and often work in essential jobs (for instance, as home health aides) in which the central infection prevention measures—namely, minimizing in-person interactions and maintaining at least six feet of distance from other people—are difficult or impossible. *Id.* ¶¶ 15, 52; *see also* Bryant Decl. ¶ 86. People with fewer resources are also more likely to live in crowded housing, without extra space that might allow isolation of a family member sick with COVID-19; more likely to rely on public transportation; and generally lack the resources available in wealthier communities to mitigate risk. Reingold Decl. ¶¶ 36, 51-54; Bryant Decl. ¶¶ 84-86. In addition, due to longstanding inequities in access to and quality of care and structural racism, people with lower incomes and people of color are more likely to suffer from certain preexisting medical conditions, such as diabetes, obesity, and hypertension, that make them high-risk for severe COVID-19 illness and fatality. Bryant Decl. ¶ 86; Reingold Decl. ¶¶ 50-53. The available data show that, after adjusting for age, Black Americans are more than 3.5 times as likely to die from COVID-19, and Latinx Americans are almost twice as likely to die, as white Americans. Reingold Decl. ¶ 51.

2. Ongoing Nature of the Pandemic

The virus will stop spreading only once there is "herd immunity," which occurs when a

[10] *See also id.*

sufficiently high percentage of the population becomes immune to an infectious disease. *Id.* ¶¶ 19, 25-26. In this context, immunity can come from either a vaccine or from previous infection. *Id.*

There is no COVID-19 vaccine, and it is unlikely that an FDA-approved vaccine will be available for widespread public use before approximately 12 to 18 months. *Id.* ¶ 22. Even when a vaccine is available, it will take time to manufacture and distribute the necessary supply. *Id.* Moreover, due to the virus's novelty, it is still unknown whether any immunity generated by previous infection lasts permanently or only for a specified period, or whether some individuals do not develop immunity at all. *Id.* ¶ 23. Even assuming infection confers permanent or long-term immunity, and even in places already hit hard by the COVID-19 pandemic, the data show that the population is very far from obtaining herd immunity based on prior infection alone. *Id.* ¶ 25.

As a result, SARS-CoV-2 transmission is likely to continue across the United States throughout 2020 and into 2021, until the development and widespread use of a vaccine. *Id.* ¶ 28. The COVID-19 pandemic may have an even more severe impact during the fall of 2020 and winter of 2021 because of the overlapping effects of influenza and respiratory syncytial virus, which peak seasonally in the fall and winter and produce many of the same symptoms as COVID-19. *Id.* ¶ 29.

In short, a diminishing number of new cases identified or deaths recorded per day, or a "flattening of the curve," does not mean the end of the pandemic or diminished harm for the individuals who will continue to become infected. *Id.* ¶ 30. It also does not prevent a new spike in the number of cases, which is expected as some businesses and schools resume in-person services and the number of person-to-person interactions increases. *Id.* ¶¶ 20, 30.

3. Infection Prevention Measures

The only known effective measure to reduce the risk of serious illness and death from COVID-19 is to prevent infection in the first place. *Id.* ¶ 15. Transmission of SARS-CoV-2 can occur in any location where there is close proximity (less than six feet) between individuals. *Id.* ¶¶

14-16. Because transmission of the virus can occur via environmental surfaces, there is also risk of spread of the virus at any location where multiple individuals touch surfaces. *Id.* ¶ 16. There is also growing evidence that the virus can become aerosolized and linger in the air after an infected person talks or coughs, for example, and then leaves the area. *Id.* ¶ 14.

Accordingly, the CDC and other public health experts have identified staying at home, avoiding close contact with other individuals (i.e., "social distancing"), and adopting a vigilant hygiene regimen, as the best measures for protecting against transmission of SARS-CoV-2. *Id.* ¶ 15. Because the coronavirus spreads even among people who do not feel sick or exhibit any symptoms, reducing in-person encounters is the best way to curb transmission. *Id.* ¶¶ 14-17.

D. Federal Actions Encouraging Telehealth and Giving Clinicians Discretion to Eliminate Unnecessary In-Person Encounters During the COVID-19 Pandemic

One critical way to decrease potential in-person contacts is through greater use of telemedicine. *Id.* ¶ 40; Bryant Decl. ¶ 74. By reducing in-person visits to medical offices and hospitals, telemedicine helps reduce the risks patients face when traveling for care and prevent health care facilities from becoming sites of transmission, while still enabling clinicians to meet their patients' essential medical needs. Reingold Decl. ¶¶ 31-42; Bryant Decl. ¶¶ 71-75.

Defendant HHS has emphatically promoted the widespread use of telemedicine during the pandemic. Reingold Decl. ¶¶ 40-47. The CDC instructs health care professionals that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19," and encourages patients to "[u]se telemedicine, if available, or communicate with your doctor or nurse by phone or e-mail." *Id.* ¶¶ 40, 42. The CDC specifically advises patients to use mail-order or delivery services, if possible, for all of their prescriptions. *Id.* ¶ 42.

To facilitate this expansion of telehealth, Defendant HHS's Office for Civil Rights ("OCR") announced that it would waive potential penalties under the Health Information and

Privacy Protection Act against health care providers that act in "good faith" to serve patients through everyday communications technologies, such as FaceTime or Zoom, during the COVID-19 emergency. The OCR Director explained: "We are empowering medical providers to serve patients wherever they are during this national public health emergency."[11]

Another HHS agency, the Centers for Medicare and Medicaid Services ("CMS"), announced in March that it would temporarily expand Medicare coverage to include a broader range of telemedicine services, Reingold Decl. ¶ 45, and in April published a toolkit to help states take advantage of "broad federal flexibility to cover telehealth through Medicaid."[12] CMS Administrator Seema Verma explained that the coverage expansion would enable patients "to communicate with their doctors without having to travel to a healthcare facility so that they can limit risk of exposure and spread of this virus. Clinicians on the frontlines will now have greater flexibility to safely treat our beneficiaries." *Id.* Defendant Secretary Azar similarly stated that this change would allow patients "to access healthcare they need from their home, without worrying about putting themselves or others at risk during the COVID-19 outbreak."[13]

Defendant FDA has likewise encouraged the use of telemedicine. For example, the agency issued guidance in March, under its authority to "protect[] the United States from threats . . .

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[11] *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, U.S. Dep't of Health & Human Servs. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html [hereinafter "OCR Announcement"].

[12] *Trump Administration Released COVID-19 Telehealth Toolkit to Accelerate State Use of Telehealth in Medicaid and* CHIP, U.S. Ctrs. for Medicare & Medicaid Servs. (Apr. 23, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-releases-covid-19-telehealth-toolkit-accelerate-state-use-telehealth-medicaid.

[13] P*resident Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak*, U.S. Ctrs. for Medicare & Medicaid Servs. (Mar. 17, 2020), https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak.

including the . . . COVID-19 pandemic," that sought to expand the use of remote patient monitoring devices. Reingold Decl. ¶ 44. As the FDA explained: "In the context of the COVID-19 public health emergency, the leveraging of current non-invasive patient monitoring technology will help eliminate unnecessary patient contact and ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 pandemic as it relates to diagnosis and treatment of patients with COVID-19 and ensuring other patients who require monitoring for conditions unrelated to COVID-19 can be monitored outside of health care facilities." *Id.*

Defendants have also relaxed in-person requirements for highly regulated drugs during the pandemic, to afford clinicians discretion to provide appropriate medical care under these emergency circumstances. *Id.* ¶ 46. On March 22, 2020, the FDA issued guidance declaring its intention not to enforce REMS requirements for laboratory testing (such as liver enzyme testing) or imaging studies (such as MRIs) for the duration of the public health emergency, as long as the decision to forgo testing or imaging was made based on the judgment of a health care professional. *Id.* In announcing its intent not to enforce other REMS, the FDA stated that, during the COVID-19 emergency, "completion of REMS-required laboratory testing or imaging studies may be difficult because patients may need to avoid public places and patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing laboratory testing or imaging studies in order to obtain a drug subject to a REMS can put patients and others at risk for transmission of the coronavirus." *Id.*

Defendant Secretary Azar similarly lifted in-person requirements for the prescription of controlled substances during the public health emergency. *Id.* ¶ 47. In consultation with the U.S. Drug Enforcement Agency ("DEA"), Defendant Azar has activated an emergency exception that

allows medical providers to prescribe controlled substances via telemedicine without first conducting an in-person examination. *Id.* In a letter to practitioners, the DEA also explained that it is "exercising its authorities to provide flexibility in the prescribing and dispensing of controlled substances to ensure necessary patient therapies remain accessible" during the public health emergency. *Id.* ¶ 48. The head of the agency stated that the DEA would continue "to explore options that ensure those in need of vital prescriptions are able to get them, while still adhering to safe practices such as social distancing." *Id.*

In accordance with public health guidance and this easing of federal restrictions, clinicians in virtually all areas of health care are using telemedicine where medically appropriate to evaluate and treat patients during the pandemic—reducing unnecessary travel and in-person encounters while still meeting patients' needs. *Id.* ¶ 49; Bryant Decl. ¶ 97; Declaration of Heather Paladine, M.D., FAAFP, attached hereto as Exhibit 3 ("Paladine Decl.") ¶¶ 12-27; Declaration of Angela Chen, M.D., M.P.H., FACOG, attached hereto as Exhibit 4 ("Chen Decl.") ¶¶ 6, 8; Declaration of Serina Floyd, M.D., M.S.P.H., FACOG, attached hereto as Exhibit 5 ("Floyd Decl.") ¶¶ 6, 11-12, 14; Declaration of Eve Espey, M.D., M.P.H., FACOG, attached hereto as Exhibit 6 ("Espey Decl.") ¶ 13; Declaration of Honor MacNaughton, M.D., attached hereto as Exhibit 7 ("MacNaughton Decl.") ¶¶ 5, 9. From management of chronic conditions, to acute treatment of infections, to prenatal and postpartum care, clinicians are using their medical judgment to care for patients remotely during this crisis. Bryant Decl. ¶ 97; Paladine Decl. ¶¶ 13, 21-26; Chen Decl. ¶¶ 13; Floyd Decl. ¶ 15; MacNaughton Decl. ¶ 9. Without the increased use of telemedicine, many more patients would go without necessary health care during this pandemic, and many more patients and health care staff would needlessly face increased exposure risks at in-person visits. Reingold Decl. ¶¶ 36-42; Bryant Decl. ¶ 97; Paladine Decl. ¶¶ 13-27; *see also* Chen Decl. ¶ 8;

Floyd Decl. ¶ 11; MacNaughton Decl. ¶ 9.

E. FDA's Retention of the Mifepristone In-Person Dispensing Requirement Despite Entreaties from Medical Authorities for Relief During the Pandemic

Recognizing the harm that the Mifepristone In-Person Dispensing Requirement is causing patients and clinicians during the COVID-19 pandemic, and the lack of any basis for the FDA's differential treatment of mifepristone prescribers and patients, for the past two months leading medical and public health experts have petitioned the FDA not to enforce the Requirement against clinicians exercising their medical judgment to appropriately mitigate burdens and risks for their patients during the pandemic. These requests include (but are not limited to):

- American Academy of Family Physicians (March 25, 2020), *see* Compl. Ex. 3;
- Nine clinics providing abortion and other reproductive health services in 16 states (March 27, 2020), *see* Compl. Ex. 4;
- Plaintiff ACOG and the Society for Maternal-Fetal Medicine (April 20, 2020), *see* Compl. Ex. 5;
- Dozens of professional associations and institutions, including Abortion Care Network, American Society for Reproductive Medicine, American College of Nurse-Midwives, Maryland Academy of Family Physicians, Massachusetts Academy of Family Physicians, Michigan Academy of Family Physicians, Minnesota Academy of Family Medicine, National Abortion Federation, Plaintiff NYSAFP, Planned Parenthood Federation of America, Reproductive Health Access Project, Washington Academy of Family Physicians, as well as hundreds of clinicians and researchers (April 28, 2020), *see* Compl. Ex. 6.

Despite these urgent requests reflecting a national medical consensus that the Requirement is needlessly harming patients and clinicians during this crisis, Defendants failed to withdraw, suspend, or declare an intention not to enforce the Requirement during the COVID-19 pandemic, and failed to provide any explanation for their constructive denial of these requests.

F. FDA's Discriminatory Treatment of Mifepristone with No Medical Basis

There is no medical basis for requiring a patient to whom mifepristone has been prescribed

to travel to a hospital, clinic, or medical office solely to obtain a medication (which she is permitted to swallow later at home) and physically sign a form (which she has already reviewed with her prescriber via telehealth) during the pandemic. Bryant Decl. ¶¶ 48-70.

Of the more than 20,000 FDA-approved drug products, the FDA subjects only 16 drugs to a REMS requiring the patient to obtain the medication in a hospital, clinic, or medical office—two of which are Mifeprex and its generic, mifepristone. *Id.* ¶ 58. For every one of these 16 drugs *except* Mifeprex and its generic, either the method by which the drug is administered requires, or the drug's prescribing information specifically states, that the drug is administered only in certain health care settings or by specified health care personnel. *Id*. Mifeprex and its generic are the *only* FDA-approved drugs for which the FDA regulates where the patient can obtain the drug, but neither specifies where the patient must take it nor requires any supervision of the patient as the drug is administered. *Id.*

Indeed, the FDA updated the Mifeprex labeling in 2016 to indicate that patients may take the mifepristone without clinical supervision at a location of their choosing, based on "studies, including those of home use of mifepristone and misoprostol, [that] show increased convenience, autonomy and privacy for the woman, . . . and no increased burden on the health care system," and that identify "safety" as among the benefits of home administration.[14] There is no safety benefit to dictating where patients receive a pill they may take at home. Bryant Decl. ¶¶ 48-70.

Moreover, as the labeling explains, the pharmacologic effects of mifepristone do not begin until hours after ingestion, and "most women will expel the pregnancy within 2 to 24 hours of taking *misoprostol*"—i.e., 26 to 72 hours after taking the mifepristone. Bryant Decl. ¶ 35; Compl.

[14] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., *Medical Review* 62 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "FDA 2016 Medical Review"].

Ex. 1, at 3. Thus, regardless of where patients take the mifepristone, they will almost never be with their prescriber when they experience the medication's effects. Bryant Decl. ¶ 56. In short, blocking a prescriber from dispensing mifepristone to their patients directly by mail, or through a mail-order pharmacy, has no bearing on whether, hours or days later, a patient will experience one of the "exceedingly rare" risks listed in the labeling, nor on how any such rare complications would be managed. *Id.* ¶ 57.

In addition, while the FDA refuses to allow clinicians prescribing mifepristone for abortion or miscarriage care to mail mifepristone directly to their patients or call in a prescription to a mail-order pharmacy even during this pandemic, the FDA has long authorized the same chemical compound to be mailed directly to patients' homes in far greater quantities when used for a different purpose. *Id.* ¶¶ 62-63. Mifepristone is also FDA-approved for marketing under the brand name Korlym® in 300 mg tablets for daily use by patients with endogenous Cushing's syndrome to treat high blood sugar caused by high cortisol levels in the blood. *Id.* ¶¶ 62-65. Korlym is *not* subject to a REMS and may be obtained from a mail-order pharmacy that delivers the drug to the patient's home. *Id.* ¶ 65. The patient then takes one to four pills (300 mg to 1200 mg—1.5 to 6 times the recommended dose for Mifeprex) daily at home according to their prescription. In a 2016 Medical Review for Mifeprex, the FDA observed that "Korlym is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex that is the subject of this supplement; the rate of adverse events with Mifeprex is much lower."[15]

The FDA also allows the mailing of misoprostol, the second drug in the FDA-approved medication abortion regimen. Misoprostol is not subject to a REMS and patients may obtain it from retail or mail-order pharmacies. Bryant Decl. ¶ 67. There is no medical basis for allowing a

[15] *Id*. at 10.

mail-order pharmacy to dispense Korlym or misoprostol to patients by prescription under all circumstances but prohibiting a mail-order pharmacy from dispensing Mifeprex by prescription even during the COVID-19 pandemic.

Defendants have singled out patients who need mifepristone for abortion and miscarriage treatment, and clinicians providing that care, for a special barrier that impedes clinicians' medical judgment during this public health crisis; subjects patients, clinicians, and other health care staff to unnecessary medical risks; and conflicts with Defendants' own efforts to mitigate the spread of COVID-19. *See* Bryant Decl. ¶¶ 48-70; Reingold Decl. ¶¶ 31-55.

G. The Impact of the Mifeprex In-Person Dispensing Requirement During COVID-19

Because of the Requirement, Plaintiffs and their members must force their patients to travel in person to a hospital, clinic, or medical office during the COVID-19 pandemic, even when the patient has already been evaluated and comprehensively counseled during a telehealth consultation or prior in-person evaluation and there is no medical reason to make the in-person trip. *See* Chen Decl. ¶¶ 13, 17-18; Espey Decl. ¶¶ 10, 12-13; Floyd Decl. ¶¶ 16-19; MacNaughton Decl. ¶¶ 10-11; Paladine Decl. ¶¶ 15-16, 19-20.

The Requirement increases SARS-CoV-2 exposure risks for patients and clinicians in at least three ways: *first*, by requiring travel, childcare arrangements, and other personal encounters as a condition of obtaining mifepristone for abortion or miscarriage care, *see* Reingold Decl. ¶¶ 35-42; *second*, by forcing patients to raise funds and make arrangements for such travel and childcare, which—particularly in the context of the pandemic and associated economic crisis—will delay some patients to the point in pregnancy when medication abortion is no longer available and they instead need an in-office procedure that requires more person-to-person contact for a longer duration of time, *see* Bryant Decl. ¶ 102; Floyd Decl. ¶¶ 20-21; Espey Decl. ¶ 12; and *third*,

by causing some patients seeking miscarriage care to use a less effective treatment regimen in order to try and minimize exposure risks and burdens, but which ultimately makes them more likely to require a subsequent in-office procedure, *see* Bryant Decl. ¶ 91.

Traveling during the pandemic imposes medical risks. Reingold Decl. ¶¶ 36, 38-41. A significant majority (75%) of people seeking abortions are poor or have lower incomes. Bryant Decl. ¶ 18. Many of these patients use public transportation, ride-sharing, or a borrowed car, to get to their appointment—all of which expose the patient to risks of infection. Reingold Decl. ¶ 36. If the patient has a car, stopping for gas or a restroom on the way to the facility, or paying for parking, also creates infection risk. *Id.*; Chen Decl. ¶ 9. Given the dearth of abortion access in many areas of the country and the frequency with which patients must travel significant distances for such care, these stops necessarily occur for many patients. Reingold Decl. ¶¶ 36, 39; Bryant Decl. ¶¶ 22-23; Espey Decl. ¶¶ 10-12. Indeed, 89% of U.S. counties lacked an abortion clinic in 2017 (the latest available data). Bryant Decl. ¶ 22.

In addition, a majority of abortion patients have at least one child, and many patients will need to arrange childcare while they travel to obtain their mifepristone. *Id.* ¶ 17. On top of being a significant cost and logistical hurdle, childcare poses serious exposure risks. *Id.* ¶ 83; Reingold Decl. ¶ 37. Indeed, it is exceedingly difficult for many people to find childcare during the COVID-19 pandemic precisely because of these infection risks, which have prompted schools, camps, and daycares to close and disrupted the social networks on which people typically rely. Reingold Decl. ¶¶ 20, 36; Bryant Decl. ¶ 83; Espey Decl. ¶¶ 11-12. Many health care facilities are not permitting children into their facilities during this pandemic (unless being treated directly) because of social distancing and infection prevention efforts. Reingold Decl. ¶ 36; *see also, e.g.*, Floyd Decl. ¶¶ 13, 22; Chen Decl. ¶¶ 10, 18; MacNaughton Decl. ¶ 12; Paladine Decl. ¶ 20. Accordingly, many

patients will have to either allow caregivers into their homes or drop their children off at someone else's home (assuming they are able to find someone willing and able to risk the exposure) or leave their children at a childcare facility (assuming they can find, and afford care at, a facility that is still open) while they travel to obtain the mifepristone, expanding person-to-person contacts without social distancing and creating other opportunities for infection. Reingold Decl. ¶¶ 35-39. If a patient is permitted to bring a child with them to the health care center, and compelled to do so for lack of childcare, that child also faces unnecessary exposure risks both at the facility and in traveling to the facility, and increases the risk to health care staff. *See, e.g.*, *id*. ¶ 41; Espey Decl. ¶¶ 11-12; Floyd Decl. ¶¶ 20, 22.

Once patients arrive at the health care center, there will often be additional exposure risks. Patients may be unable to maintain complete social distancing with other patients or health care staff even before they reach the location where they will receive their pill, particularly at entrances and in common areas of the facility. Reingold Decl. ¶ 38. In many cases, they will have to touch doors, elevators, and/or other surfaces within the hospital, clinic, or medical office. *Id*. To obtain the mifepristone pill and provide the incidental signature on paperwork required by the REMS, patients will likely need to have close contact with at least one health care professional. *Id*. Even though health care professionals are very well versed in infection control, these encounters still necessarily carry some risk. *Id.* ¶¶ 21, 35, 38. While abortion and miscarriage care are essential services to which patients must retain access during the pandemic, Defendants make accessing such care needlessly risky. *See* Bryant Decl. ¶ 106.

This travel and social contact necessitated by the Mifepristone In-Person Dispensing Requirement is directly contrary to guidance issued by the CDC within Defendant HHS. Reingold Decl. ¶¶ 40-43. For instance, the CDC advises people to stay at home and avoid travel, including

local travel, specifically cautioning that bus or train travel, or gas or rest stops during car travel, will expose individuals to infection risk. *Id.* ¶ 41. The CDC emphasizes that children, like adults, should maintain social distancing and not have close contact with those outside the immediate household. *Id.* For purchases, the CDC stresses that individuals should "[o]rder food and other items online for home delivery or curbside pickup (if possible). Only visit the grocery store, or other stores selling household essentials, in person when you absolutely need to." *Id.* ¶ 43. The CDC specifically advises patients to limit visits to pick up medications, and to use mail-order or delivery services, if possible, for all of their prescriptions. *Id.* ¶ 42.

For the mostly poor and low-income patients seeking abortion care, such travel and associated expenses will also often lead to delays that, in turn, increase medical risk. Bryant Decl. ¶¶ 92-105. Research has long shown that the costs and logistics associated with having to travel for an abortion delay patients' access to care. *Id.* ¶ 99. During the COVID-19 pandemic and associated unemployment crisis, low-income patients are particularly likely to struggle to pay for and arrange travel. *Id.* ¶ 92. Already as of late April, 43% of U.S. adults reported that they or someone in their household had lost a job or taken a cut in pay due to the pandemic, and among lower-income adults, 52% said they or someone in their household had experienced direct negative impact on their take-home pay. Bryant Decl. ¶ 93. In the same month, more than half (53%) of lower-income adults said they would have trouble paying some of their bills that month. *Id.* ¶ 94. Moreover, as noted above, COVID-19 has closed schools and childcare facilities and upended many of the familial and social networks on which people would typically rely for childcare assistance or to borrow a car or get a ride. *Id.* ¶ 95.

Many patients suffering from intimate partner violence face additional challenges in accessing abortion care, even under normal circumstances. *Id.* ¶ 96. Abusers often sabotage their

partners' efforts to avoid pregnancy; isolate them from their networks of friends and family; and deprive them of money, access to transportation, and access to health care. *Id.* ¶¶ 21, 96. COVID-19, the associated economic fallout, and self-isolation and social distancing guidelines in response to the pandemic, all threaten to exacerbate these obstacles and burdens. *Id.* ¶ 96.

Because the Requirement substantially increases the costs, risks, and logistical challenges of accessing abortion care during the COVID-19 pandemic, some patients will be delayed to the point when they cannot obtain a medication abortion at all, and will instead have to incur the greater exposure risks associated with an in-office procedural abortion. Bryant Decl. ¶ 102; *see also* Floyd Decl. ¶¶ 20-21; Espey Decl. ¶ 12. Indeed, patients who have been exposed to SARS-CoV-2 or are exhibiting any symptoms of COVID-19 may have no choice but to delay their abortion by 14 days, or until they can obtain a negative test, based on the facility's quarantine policy. Bryant Decl. ¶ 100; MacNaughton Decl. ¶ 15. The Requirement denies such patients the option to receive care promptly without ever having to leave their homes.

The needless medical risks imposed by the Mifepristone In-Person Dispensing Requirement during COVID-19 are particularly dangerous for people of color, who comprise a majority of abortion patients and a disproportionate share of patients experiencing miscarriages; who generally have fewer resources at their disposal to mitigate risks; and who are suffering from severe illness and fatality from COVID-19 at dramatically heightened rates. Bryant Decl. ¶¶ 19, 25, 86; Reingold Decl. ¶¶ 51, 53; Declaration of Monica Simpson, attached hereto as Exhibit 8, ¶¶ 4, 7; Floyd Decl. ¶¶ 7, 28; Espey Decl. ¶¶ 9-10; Paladine Decl. ¶¶ 9-11, 19-20.

Because of the nature of SARS-CoV-2 transmission, the harm that the Mifepristone In-Person Dispensing Requirement imposes has repercussions far beyond the patients themselves. Reingold Decl. ¶¶ 35, 54-55. This is particularly true for low-income people, people of color, and

immigrants, who are more likely to work in essential jobs, where they will continue to have contact with other members of the community, and more likely to live in intergenerational or multi-family housing where introducing the virus puts others, including elderly family members, at severe risk. Reingold Decl. ¶¶ 50-55; Bryant Decl. ¶ 86; *see also* Paladine Decl. ¶¶ 9-11, 19.

III. STANDARD OF REVIEW

To obtain a preliminary injunction, "the plaintiff must establish '[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.'" *Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 346 (4th Cir. 2009) (citations omitted).

IV. ARGUMENT

A. Plaintiffs Are Likely to Prevail on the Merits Because Defendants Subject Mifepristone to a Unique In-Person Dispensing Requirement that Poses Life-Threatening Risks to Patients and Clinicians with No Countervailing Benefit.

Because the Requirement serves no medical purpose nor any other conceivable interest; imposes serious medical risks on patients seeking to access abortion or miscarriage care during the pandemic; and singles out a class of patients and clinicians for discriminatory treatment, Plaintiffs are likely to prevail in proving that it violates the protections of the U.S. Constitution.

1. Plaintiffs are Likely to Succeed in Proving that the Requirement Imposes an Undue Burden During the COVID-19 Pandemic.

"Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016); *Richmond Med. Ctr. for Women v. Gilmore*, 55 F. Supp. 2d 441, 481 (E.D. Va. 1999), *aff'd*, 224 F.3d 337 (4th Cir. 2000). In assessing whether a restriction on abortion unduly burdens access, courts must balance "the burdens a law imposes

on abortion access together with the benefits th[e] law[] confer[s]." *Whole Woman's Health*, 136 S. Ct. at 2309 (citation omitted). Applying this balancing test in 2016, the Supreme Court permanently enjoined two laws that regulated clinicians providing abortion care in the name of patient safety, finding "no significant health-related problem that [the laws] helped to cure," and concluding "that neither . . . confers medical benefits sufficient to justify the burdens upon access that each imposes." *Id.* at 2311, 2299.

Plaintiffs are likely to succeed in proving that the Mifepristone In-Person Dispensing Requirement imposes an undue burden on abortion access during the COVID-19 pandemic. Forcing a patient to travel in person to a hospital, clinic, or medical office to pick up a pill she will swallow unsupervised at home offers no medical benefit. And, in the present circumstances, any conceivable benefit is far outweighed by the burdens it imposes on patients seeking care: needless exposure to the severe risks of illness and death associated with COVID-19. *See, e.g.*, *Thomas v. Andino*, No. 3:20-cv-01552-JMC, at *33 n.20 & 40 (D.S.C. May 25, 2020) (finding plaintiffs likely to prevail in constitutional challenge to witness requirement for absentee ballots because "the burdens imposed on [plaintiffs] in having to place their health at risk during the COVID-19 pandemic likely outweigh the extent to which the Witness Requirement advances the state's interests of voter fraud and integrity" and the law "forces voters to make the untenable and illusory choice between exercising their right to vote and placing themselves at risk of contracting a potentially terminal disease").

a. The Requirement Provides No Medical Benefit.

The Requirement is medically unnecessary and illogical on its face: it requires patients to obtain a pill only in clinical settings, even when they are not receiving any clinical services at that time and will take the medicine at home without clinical supervision. There is *no* other drug that the FDA treats in this manner, Bryant Decl. ¶¶ 58-61, and for evident reason: it plainly serves no

medical interest to dictate where a patient is standing when handed a pill she will put in her pocket to swallow later, *id.* ¶ 56.

This Requirement is particularly ill-fitting for a medication like mifepristone, for which serious complications are, in the FDA's words, "extremely rare" and, even in such rare cases, would not manifest until hours or days later. *Id.* ¶ 56; *see also Whole Woman's Health*, 136 S. Ct. at 2315 (abortion facility law at issue "provide[d] no benefit" where medication abortion "complications would almost always arise only after the patient has left the facility."). There is thus "no significant health-related problem" that the Requirement "help[s] to cure." *Id.* at 2311.

b. The Requirement Imposes Severe Burdens.

Where an abortion restriction is "sought to be justified on medical grounds… [t]he feebler the medical grounds, the likelier the burden, even if slight, is to be 'undue.'" *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 914 (9th Cir. 2014) (quoting *Planned Parenthood of Wisc., Inc. v. Van Hollen*, 738 F.3d 786, 798 (7th Cir. 2013)). Because the Mifepristone In-Person Dispensing Requirement offers no medical benefit, even minimal burdens could not pass constitutional muster. But this case presents a far more lopsided scale: the Requirement forces patients to incur the unnecessary risk of contracting a life-threatening illness to comply with a mandate that serves no medical purpose.

The Requirement forces patients to engage in unnecessary travel and in-person interactions during a pandemic that is spread through personal encounters and shared spaces, and for which there is no known vaccine, as a condition of obtaining abortion care. This risk is especially grave for low-income people and people of color, who comprise the majority of abortion patients; are more likely to suffer severe COVID-19 illness and fatality; and are more likely to live in multi-family or intergenerational homes where their COVID-19 exposure also threatens the safety of others, including elderly family members. Bryant Decl. ¶ 86; Reingold Decl. ¶¶ 50-55; *see*

Humble, 753 F.3d at 915 (courts conducting undue burden analysis may "consider the ways in which an abortion regulation interacts with women's lived experience [and] socioeconomic factors").

Courts have repeatedly recognized that forcing patients to take on increased medical risk in order to obtain an abortion is a heavy burden. *See, e.g.*, *Humble*, 753 F.3d at 915-916 (affirming injunction of law prohibiting evidence-based off-label use of mifepristone in part because the restriction "may delay abortions, thereby increasing health risks"); *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1326-27 (11th Cir. 2018), *cert. denied sub nom. Harris v. W. Alabama Women's Ctr.*, 139 S. Ct. 2606 (2019) (affirming injunction of law requiring abortion technique that could pose "serious health risks" for some patients); *Planned Parenthood of Wisc., Inc. v. Schimel*, 806 F.3d 908, 918 (7th Cir. 2015) (affirming injunction of law that would cause some patients "to forgo first-trimester abortions and instead get second-trimester ones, which . . . present greater health risks"). Indeed, the Supreme Court has considered even less tangible health care burdens, such as whether a law would result in "fewer doctors, longer waiting times, and increased crowding," with patients "less likely to get the kind of individualized attention, serious conversation, and emotional support that doctors at less taxed facilities may have offered," in invalidating restrictions on abortion care. *Whole Woman's Health*, 136 S. Ct. at 2318. Against this legal backdrop, Plaintiffs are likely to prevail in proving that the severe medical risks the Requirement imposes on patients seeking medication abortion care during the COVID-19 pandemic outweighs its non-existent benefits.

Moreover, as the nation struggles with a historic economic depression, the Requirement exacerbates the burdens that many abortion patients already faced in attempting to pay for and arrange transportation and childcare to obtain this time-sensitive medical care. This, in turn forces

some patients to delay their care and as a result face increased medical risk. Bryant Decl. ¶ 101; Chen Decl. ¶¶ 9-11, 18; Floyd Decl. ¶¶ 20-22; MacNaughton Decl. ¶¶ 12-13. *See, e.g.*, *Whole Woman's Health*, 136 S. Ct. at 2302 (highlighting district court's findings that burdens would "erect a particularly high barrier for poor, rural, or disadvantaged women"); *Robinson v. Attorney Gen.*, 957 F.3d 1171, 1180 (11th Cir. 2020) (recognizing that the "obstacles women face in seeking to obtain an abortion—such as difficulty traveling to a clinic, receiving necessary time off, arranging child care, or affording an abortion in the first place—would be 'greatly exacerbate[d]' by a mandatory delay, particularly "in the midst of a pandemic that has yielded widespread job loss, financial difficulty, and social isolation"); *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r* (*"PPINK"*), 896 F.3d 809, 819 (7th Cir. 2018) (blocking ultrasound requirement for abortion based on the travel it required and the strain this imposed on "realm of finances, employment, child care, and domestic safety," particularly for low-income patients), *petition for cert. docketed sub nom. Box v. Planned Parenthood of Ind. & Ky., Inc.* (Feb. 4, 2019); *Williamson*, 900 F.3d at 1326–27 (11th Cir. 2018) (affirming injunction where law would increase medical risk and "increase the costs of travel and lodging for women who do not live near the plaintiff clinics," which "would be especially burdensome for low-income women").

2. Plaintiffs are Likely to Succeed in Proving that the Requirement Violates Equal Protection.

The constitutional principle of equal protection "directs that 'all persons similarly circumstanced shall be treated alike.'" *Plyler v. Doe*, 457 U.S. 202, 216 (1982) (citation omitted); *see also Morrison v. Garraghty*, 239 F.3d 648, 654 (4th Cir. 2001) (equal protection "keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike") (citation omitted). Because the Requirement "impinges on personal rights protected by the Constitution," *see supra*, it is subject to heightened scrutiny. *City of Cleburne, Tex. v. Cleburne*

Living Ctr., 473 U.S. 432, 440 (1985). But Plaintiffs are likely to prevail under any level of scrutiny because the classification here cannot withstand even rational basis review.

Courts must set aside government classifications that cannot be rationally explained and that therefore impose arbitrary harms on those subjected to them. *See, e.g.*, *id.* at 448 ("The question is whether it is rational to treat the mentally [disabled] differently. It is true that they suffer disability not shared by others; but why this difference warrants a density regulation that others need not observe is not at all apparent."); *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 533 (1973) (rejecting exclusion of one type of household from access to food stamps as "wholly without rational basis"); *Lindsey v. Normet*, 405 U.S. 56, 77-79 (1972) (holding that a bond requirement arbitrarily deprived poor tenants of eviction appeals). Here, Plaintiffs are likely to succeed in showing that Defendants have violated equal protection by irrationally requiring mifepristone prescribers to dispense pills to their patients onsite during the COVID-19 pandemic while otherwise facilitating clinicians' ability to avoid unnecessary in-person visits in accordance with their professional judgment. Defendants' conduct arbitrarily imposes an increased risk of COVID-19 infection on patients seeking medication abortion or miscarriage care, and the clinicians providing that care, for no rational and legitimate reason.

a. The Requirement Sharply Contrasts with Defendants' Treatment of Similarly Situated Patients and Clinicians.

As the number of reported cases and confirmed deaths in the United States began accelerating in March, Defendants quickly acted to reduce unnecessary travel to and in-person contact at health care facilities, including by "[l]everaging telemedicine whenever possible . . . . " Reingold Decl. ¶¶ 40-47. On March 16, Defendant Secretary Azar worked with the DEA to ease requirements that an authorized prescriber conduct at least one in-person evaluation of the patient before prescribing many controlled substances, allowing, for example, clinicians to prescribe

opioids solely via telemedicine. *Id.* ¶ 47. The next day, on March 17, Defendant HHS announced that it was "empowering medical providers to serve patients wherever they are during this national public health emergency" by authorizing the use of technologies like FaceTime and Zoom for "good faith" telehealth use.[16] On March 22, Defendants waived enforcement of certain REMS requirements mandating in-person testing, such as liver enzyme testing or MRI studies that—unlike Mifepristone In-Person Dispensing Requirement—serve a meaningful medical purpose. Reingold Decl. ¶ 46. Defendants have taken numerous other actions to reduce unnecessary health care travel and in-person interactions during the pandemic, including encouraging mail-order delivery of prescriptions. *Id.* ¶¶ 40-49.

Nevertheless, Defendants have refused to waive or otherwise halt enforcement of the Mifepristone In-Person Dispensing Requirement during the COVID-19 crisis, *de facto* denying the repeated requests by Plaintiffs and other leading medical authorities, submitted throughout March and April, asking Defendants to afford mifepristone prescribers the same discretion as other clinicians to protect their patients, their staff, and themselves from needless viral exposure.

b. There is No Rational Justification for Maintaining the Requirement.

Allowing eligible patients to receive mifepristone by mail in accordance with their clinicians' judgment in no way alters the mifepristone-misoprostol treatment regimen, its extremely minimal safety risks, or how care would be managed in the "exceedingly rare" event of a serious complication. Bryant Decl. ¶ 42 (quoting Defendant FDA). The FDA already allows mifepristone prescribers to exercise their clinical judgment in determining whether a patient's eligibility can be assessed through telehealth or based on a prior in-person visit, or whether an additional in-person assessment is indicated. *Id.* ¶¶ 49-50. The FDA also already allows patients

[16] OCR Announcement, *supra* note 10.

to take the medication at home. *Id.* ¶ 33. The only change Plaintiffs seek is the elimination of the requirement that patients travel to a health care facility to pick up the pill.

Defendants' retention of the Requirement during the pandemic cannot be explained by any inherent dangerousness in Mifeprex or its generic: Defendants already allow another mifepristone product, Korlym, to be mailed directly to patients' homes in larger doses and far greater quantities, and admit that "the rate of adverse events with Mifeprex is much lower."[17]

Nor can Defendants' treatment of mifepristone be rationally justified by analogy to medications that can be safely administered only by certain clinical personnel in certain clinical settings, or that must be administered under a clinician's supervision because of the risk of immediate complications. *See* Bryant Decl. ¶ 61. The FDA does not require in-person administration of mifepristone. *Id.* To the contrary, based on evidence showing the "safety," "convenience, autonomy, and privacy" of home administration of mifepristone and misoprostol,[18] the FDA authorizes patients to take both medications at the location(s) of their choosing in accordance with the prescriber's instructions. Bryant Decl. ¶ 33; Compl. Ex. 1, at 3. Moreover, the pharmacologic effects of mifepristone do not begin until hours after ingestion, and most patients will not pass the pregnancy until 26 to 72 hours after taking the pill. Bryant Decl. ¶ 35; Compl. Ex. 1, at 3. Thus, regardless of where patients take the mifepristone, they will almost never be with their prescriber by the time they experience its effects. Bryant Decl. ¶ 56.

Finally, the REMS requirements incidental to the in-person pick-up—that the patient physically sign the Patient Form; that the clinician hand the patient a copy of the form onsite, rather than electronically or with the pill by mail; and that the clinician be the one to record the serial

[17] FDA 2016 Medical Review, *supra* note 13, at 10.
[18] *Id.* at 62.

number of the medication, rather than a pharmacist—add no medical benefit. Like all other clinicians, mifepristone prescribers can (and already do) comprehensively counsel and obtain consent from patients—including reviewing the paperwork required by the REMS and answering any patient questions—using telehealth technologies. Bryant Decl. ¶ 31; *see also, e.g.*, Chen Decl. ¶¶ 14-15. Whether patients give consent orally documented by their prescriber; through technologies allowing remote signatures; or, as is currently required, in person when obtaining the pill, has no bearing on the quality or efficacy of the counseling or consent. Bryant Decl. ¶ 70.

The Requirement is a singular restriction even under normal circumstances: the only drug out of 20,000 that must be picked up onsite but can be self-administered at home. Bryant Decl. ¶ 58. During the pandemic, this discrimination is magnified: Defendants are denying clinicians prescribing mifepristone for abortion or miscarriage care the discretion afforded to other clinicians during this emergency, and subjecting their patients to life-threatening risks, without advancing *any* conceivable, legitimate interest. Just as the barriers erected in *Cleburne*, *Moreno*, and *Lindsey* were arbitrary and unenforceable, so too is the Requirement. Defendants' singular treatment of mifepristone "fails to pass muster under even the most deferential form of scrutiny." *Roe v. Shanahan*, 359 F. Supp. 3d 382, 413 (E.D. Va. 2019) (finding likelihood of success on equal protection against policy that barred all HIV-positive servicemembers from deployments without any individualized assessment, contrary to the military's approach to other chronic conditions), *aff'd* 947 F.3d 207 (4th Cir. 2020), *as amended* (Jan. 14, 2020).

B. The Mifeprex In-Person Dispensing Requirement is Causing Irreparable Harm to Plaintiffs' Members and Their Patients.

Because the Mifepristone In-Person Dispensing Requirement violates constitutional rights, it unquestionably causes irreparable injury. *See, e.g.*, *Ross v. Messe*, 818 F.2d 1132, 1135 (4th Cir. 1987) ("the denial of a constitutional right . . . constitutes irreparable harm"); *Int'l Refugee*

Assistance Project v. Trump, 883 F.3d 233, 270 (4th Cir. 2018) (en banc), *cert. granted, vacated and remanded on other grounds,* 138 S. Ct. 2710 (2018); *Am. Civil Liberties Union of Ky. v. McCreary Cty.*, 354 F.3d 438, 445 (6th Cir. 2003) (when "a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated." (citing *Elrod v. Burns*, 96 S. Ct. 2673, 2689-90 (1976))), *aff'd*, 125 S. Ct. 2722 (2005).

Moreover, the Requirement needlessly exposes Plaintiffs' members, their patients, and their families to increased risk of life-threatening disease, and constrains Plaintiffs and their members from exercising their clinical judgment to provide the safest possible care. This, too, is unequivocally irreparable harm. *See, e.g.*, *Coreas v. Bounds*, No. CV TDC-20-0780, 2020 WL 1663133, at *13 (D. Md. Apr. 3, 2020) (finding COVID-19 exposure risks irreparable harm); *Banks v. Booth*, No. CV 20-849(CKK), 2020 WL 1914896, at *11 (D.D.C. Apr. 19, 2020) (same); *PPINK*, 896 F.3d at 832 (irreparable harm where law delays abortion access, making it "less safe"); *Richmond Med. Ctr. for Women v. Gilmore*, 11 F. Supp. 2d 795, 809 (E.D. Va. 1998) (irreparable injury where physicians would be "constrained to alter their medical advice to, and their medical care of, their patients contrary to their best medical professional judgments").

C. The Balance of Equities Weighs Heavily in Plaintiffs' Favor and the Injunction Serves the Public Interest, Because Preliminarily Enjoining Enforcement of the Mifepristone In-Person Dispending Requirement Will Cause Defendants No Harm While Reducing the Spread of COVID-19 Across the Country.

The balance of equities tips decisively in favor of the Plaintiffs and an injunction is in the public interest.[19] While the constitutional injury that the Requirement causes Plaintiffs, their members, and their patients during the pandemic is sufficient alone for injunctive relief, there are other urgent public interests at stake. *See e.g.*, *Thomas*, 2020 WL 2617329, at *43 ("The public

[19] "Where, as here, the injunctive relief is sought against the federal government and implicates a matter of great public interest, these two factors overlap and may be considered together." *Roe*, 359 F. Supp. 3d at 420 (citing *Nken v. Holder*, 556 U.S. 418, 436 (2009)).

interest is clearly in . . . preventing the further spread of disease. This is particularly true in the context of the "worst pandemic this state, country, and planet has seen in over a century.") (internal quotations omitted). The Requirement jeopardizes the safety not only of patients seeking abortion or miscarriage care, their clinicians, and other health care staff—but also that of the family members to whom they return; the neighbors with whom they share public transportation; and other members of the public with whom they will interact the next day.

As the Fourth Circuit has explained, the government "is in no way harmed by issuance of a preliminary injunction which prevents [it] from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction." *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 191 (4th Cir. 2013) (en banc) (quoting *Giovani Carandola, Ltd. v. Bason*, 303 F.3d 507, 521 (4th Cir. 2002)). Similarly, "upholding constitutional rights surely serves the public interest." *Giovani Carandola*, 303 F.3d at 521. This is particularly so where the constitutional violation not only injures Plaintiffs, but "in the process permeates and ripples across entire . . . communities, and society at large." *Int'l Refugee Assistance Project v. Trump*, 857 F.3d 554, 604 (4th Cir. 2017), *as amended* (May 31, 2017; June 15, 2017), *vacated and remanded on other grounds*, *Trump v. Int'l Refugee Assistance*, 138 S. Ct. 353 (2017).

V. CONCLUSION AND PROPOSED RELIEF

Because Plaintiffs are likely to succeed in proving that the Mifepristone In-Person Dispensing Requirement violates the U.S. Constitution; the Requirement is causing irreparable constitutional, medical, and other harms; and enjoining it will cause Defendants no harm while mitigating the spread of SARS-CoV-2, preliminary injunctive relief is warranted and necessary.

To afford Plaintiffs complete relief and protect the public interest, Defendants should be enjoined from any enforcement of the Mifepristone In-Person Dispensing Requirement against Plaintiffs and their tens of thousands of members, *see, e.g.*, Declaration of Tomara Lee, attached

hereto as Exhibit 9, ¶ 5; all similarly situated mifepristone prescribers; and any other individuals involved in implementing this Court's relief (such as the drug manufacturer or a mail-order pharmacy), until such time as Defendants demonstrate that the pandemic is over and medically unnecessary travel to and visits at health care facilities no longer pose a significant threat of SARS-CoV-2 transmission and illness associated with COVID-19.

As the Fourth Circuit has reasoned, granting injunctive relief that protects all similarly situated individuals is, in this type of case, "the only way to ensure uniform, fair, rational treatment of individuals who belong to a vulnerable, and often invisible," group—here, people seeking abortion or miscarriage care. *Roe v. Dep't of Defense*, 947 F.3d 207, 233-34 (4th Cir. 2020) (citation omitted). Moreover, given the nature of the harm, a preliminary injunction that extends to Plaintiffs, their members, and all similarly situated mifepristone prescribers, is proper: a patient's ability to avoid unnecessary viral exposure when obtaining abortion or miscarriage care should not turn on their clinician's professional membership affiliations. *See Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (letting stand injunction that covered non-parties similarly situated to respondents). Enjoining any enforcement of the Requirement until the pandemic is over and SARS-CoV-2 no longer poses a significant threat is the only way to afford complete relief and serve the broader public interest.

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Respectfully submitted,

/s/ John A. Freedman

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**Pro hac vice* application forthcoming

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5(a).

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